



SEMI-ANNUAL RESEARCH REPORT

July-December 2012

Acknowledgements

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Executive Summary

Every six months the AMPATH Research Program compiles reports from investigators involved in more than 110 open research studies at AMPATH in Western Kenya. The following report represents our collective progress from July to December 2012 and highlights the collaborative efforts of investigators from 15 academic institutions in North America and Kenya. These studies provide critical clinical research and bioethics training opportunities for Kenyan students, increase understanding of persistent health challenges like drug resistant HIV, TB, and malaria, and help improve clinical care for chronic diseases like cancer, diabetes, and heart disease.

The *July – December 2012 Semi Annual Report* includes updates from 53 studies examining some of the most persistent health challenges in Kenya. It includes reports from 13 new studies, which have started work at AMPATH sites since June 2012. The addition of these studies has increased AMPATH's overall research program portfolio by nearly US\$ 4.5 million in grant support from the NIH, USAID, WHO, and numerous other sponsors such as the Bill and Melinda Gates Foundation and the Walther Cancer Foundation. In addition, more than 50 new publications appearing in peer reviewed journals have been published by AMPATH investigators since June 2012.

This report describes a research program that has grown rapidly over the last decade. It is intended to showcase our program's progress and help investigators identify opportunities to develop additional research. Updates were collected from project teams using an online survey and include a list of project team members, AMPATH project sites, sponsors and awards, a general project overview, and a brief description of progress made since June 2012. The report concludes with a bibliography of AMPATH research publications.

We hope you will visit the Research Program Website, www.medicine.iu.edu/ampathresearch, to find previous semiannual reports and additional information on how AMPATH's research programs are helping improve the health of the Kenyan people.

Research Project Updates

Project Name:	A5225/HiFLAC Protocol – A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis		
Investigator(s):	Sidle, J. Siika, A. Lagat, D.		
Start Date:	5/18/2011	End Date:	12/31/2013
Sponsors:	The National Institute of Allergy and Infectious Diseases	Direct Cost (USD):	Not Reported
Site(s):	Moi Teaching and Referral Hospital (MTRH)		
Project Description:	<p>A5225/HiFLAC is a phase I/II dose escalation and validation study of the safety, tolerability, and therapeutic effect of an induction-consolidation strategy of high-dose fluconazole alone for the treatment of cryptococcal meningitis (CM) in HIV-infected participants. The study will proceed in two stages. In Stage 1, Dose Escalation, up to three induction doses of fluconazole will be tested in sequentially enrolled cohorts. Stage 2, Dose Validation, will not open until the maximum tolerated dose (MTD) of fluconazole has been identified in Stage 1.</p> <p>In Stage 2, induction doses of fluconazole that are found to be safe in Stage 1 will be tested in simultaneously enrolled cohorts.</p> <p>In each stage, participants will be randomized at entry into Step 1. Over the course of the study, participants will register to subsequent steps (Steps 2-4) based on their initial randomization and/or their response to treatment. The study steps are:</p> <ul style="list-style-type: none"> • Step 1: Induction therapy with either high dose fluconazole or ampho B • Step 2: Induction following early ampho B intolerance (only for participants randomized to ampho B treatment in Step 1) (fluconazole at 400-800 mg daily) • Step 3: Consolidation therapy (fluconazole 400 mg daily) • Step 4: Maintenance therapy (fluconazole 200 mg daily) 		
Update:	The site enrolled a total of 14 participants into cohorts 1 and 2 of the protocol. Currently cohort 3 is open to accrual but the site has not enrolled any participants into this new cohort. IREC suspended accrual of new participants in August 2012 due to high mortality rate (3 deaths out of 14). This suspension has since been lifted following provision of relevant data on mortality amongst patients with cryptococcal meningitis in several countries. The site is currently looking for potential participants to recruit.		
Project Name:	A Population-wide Home-Based Study of Hypertension Prevalence in Western Kenya		
Investigator(s):	Velazquez, E. Kimaiyo, S.		

	Akwanalo, C. Bloomfield, J. Hogan, J. Maghasi, M. Anstrom, K.		
Start Date:	2/1/2012	End Date:	12/31/2013
Sponsors:	NIH/NHLBI	Direct Cost (USD):	\$20,000
Site(s):	Mosoriot		
Project Description:	<p>Hypertension is one of the increasingly important health challenges facing the African continent and yet data on true community prevalence of hypertension in sub-Saharan Africa (SSA) is limited. The prevalence of hypertension in truly rural populations was said to be a rarity but this must have changed because of adoption of Western lifestyle. Recent studies indicate that the prevalence of hypertension and its clinically important outcomes is steadily increasing in SSA, more in the urban compared to semi urban and rural communities.</p> <p>The study will be conducted in two phases. Phase one of the study will be a cross sectional study which will be conducted on persons aged 18yrs or older from Mutwot location, Kosirai division, to assess for hypertension and diabetes mellitus. Diagnosis of hypertension and diabetes will be based on the JNC 7 and American diabetes association criteria. In the second phase of the study those individuals who are newly diagnosed with hypertension (at least 193 cases) will be assessed for target organ damage and compared to controls (386) in a 1 to 2 ratio. Target organ damage will be defined as the detection of electrocardiogram-left ventricular hypertrophy (ECG-LVH), micro albuminuria, or history of a stroke.</p>		
Update:	<p>We obtained IREC approval in August 2011 and NHLBI approval in December 2011. Training of counselors and research assistants on Diabetes and Hypertension screening and use of phone technology in data entry was completed in 2011 and included the online CITI Human Subjects Protection course.</p> <p>Since recruitment and screening for this study began in February 2012, the team has screened 1,586 patients in the Kosirai Division. Of these, 230 patients were referred to the clinic for confirmation of high blood pressure and 119 of referred patients have presented to the clinic. A total of 114 patients have been diagnosed with Hypertension and 5 with diabetes.</p> <p>We are currently awaiting IREC approval to begin a community outreach effort with the goal of tracing the participants who have not presented to the clinic.</p> <p>The following challenges have been identified thus far:</p> <ul style="list-style-type: none"> • Screened patients do not report to designated health facilities due to lack of transport • Stigma related to HIV since HIV testing is being performed at the same time as blood pressure and diabetes testing. 		

Project Name:	A Retrospective Analysis of Pregnancy Outcomes of HIV-Infected Women Enrolled in The AMPATH Program		
Investigator(s):	Bell, A. Were, E. Musick, B. Lane, K. Washington, S. Shen, C. Akhaabi, P. Hogan, J. Wools-Kaloustian, K.		
Start Date:	3/1/2006	End Date:	5/31/2013
Sponsors:	Not Reported	Direct Cost (USD):	Not Reported
Site(s):	All Sites		
Project Description:	<p>This is a retrospective analysis of pregnancy outcomes of HIV-infected women enrolled in the AMPATH program from January 2006 to March 2009. Per protocol, pregnant women with CD4 < 200 begin cART immediately and those with a CD4 ≥ 200 start at 28 weeks gestation. The pregnancy outcomes are being compared between women pregnant at program enrollment (BE) and those who became pregnant after enrollment (AE). The specific hypotheses include:</p> <ul style="list-style-type: none"> • Women who are already enrolled in the AMPATH program at the time of pregnancy diagnosis are more likely to initiate ART sooner (at a lower gestational age) than those who are not in the program prior to pregnancy diagnosis. • Women who are already enrolled in AMPATH at the time of pregnancy diagnosis are less likely to give birth to an HIV-infected baby than those who are not enrolled in the program prior to pregnancy diagnosis. • Women who are already enrolled in AMPATH at the time of pregnancy diagnosis will have better retention and adherence rates than those who are not enrolled in the program prior to pregnancy diagnosis. • Women who are already enrolled in the AMPATH program will have a lower rate of stillbirth and infant loss than those who are not enrolled in the program prior to pregnancy diagnosis. 		
Update:	The preliminary findings were presented on January 10, 2012 at the 2 nd International Conference on HIV and Women in Bethesda, Maryland. Feedback from the conferees was incorporated into the analysis plan. The dataset has been revised significantly. The analysis is underway. We expect to submit the manuscript for publication during the next quarter.		
Project Name:	A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)		

Investigator(s):	Papas, R. Gakinya, B. Martino, S. Maisto, S. Baliddawa, J. Sidle, J. Hogan, J. Carroll, K.		
Start Date:	11/1/2011	End Date:	8/31/2016
Sponsors:	NIAAA	Direct Cost (USD):	\$2,268,832
Site(s):	MTRH, Turbo, Webuye Hospital, Iten		
Project Description:	This study will determine whether a group cognitive-behavioral therapy intervention that demonstrates preliminary evidence of reducing alcohol use among HIV-infected outpatients in western Kenya is effective when compared against a group health education intervention in a large sample over a longer period of time. It will be delivered by paraprofessionals, individuals with limited professional training. This approach is consistent with successful cost-effective models of service delivery in resource-limited settings in which paraprofessionals (e.g., clinical officers, traditional birth attendants and peer counselors) are trained.		
Update:	Recruitment for the trial began in July 2012. We have since completed recruitment and randomization of 3 intervention cohorts, for a total of 92 participants. Participants have completed a 6-week group cognitive behavioral therapy or health education intervention delivered by paraprofessional counselors. Follow-ups for participants who have completed the intervention stage began in October and are ongoing. Target recruitment goals have been met and retention has been excellent.		
Project Name:	A5264/AMC067 – A Randomized Evaluation of Antiretroviral Therapy Alone or with Delayed Chemotherapy versus Antiretroviral Therapy with Immediate Adjunctive Chemotherapy for Treatment of Limited Stage AIDS-KS in Resource-Limited Settings (REACT-KS)		
Investigator(s):	Siika, A. Busakhala, N. Njiru, E.		
Start Date:	11/28/2012	End Date:	Not Reported
Sponsors:	National Institute of Allergy and Infectious Diseases (NIAID), National Cancer Institute (NCI), and National Institute of Dental Craniofacial Research (NIDCR)	Direct Cost (USD):	Not Reported
Site(s):	MTRH		

Project Description:	A5264/AMC 067 is a phase III, open-label, prospective, randomized study stratified by CD4+ lymphocyte cell count and antiretroviral therapy (ART) history. The study will compare the KS tumor outcomes of ART alone or with delayed Etoposide (ET) to ART with immediate ET, for initial treatment of limited stage AIDS-KS in chemotherapy and radiation treatment naïve HIV-1 infected participants who are currently not receiving ART		
Update:	A total of 3 participants have been enrolled at Eldoret, Kenya site.		
Project Name:	A5265 – A Phase III, Open-Label, Randomized, Assessment-Blinded Clinical Trial to Compare the Safety and Efficacy of Topical Gentian Violet to that of Nystatin Oral Suspension for the Treatment of Oropharyngeal Candidiasis in HIV-1 Infected Participants in Non-U.S. Settings		
Investigator(s):	Siika, A. Lagat, D.		
Start Date:	2/1/2012	End Date:	12/31/2012
Sponsors:	The National Institute of Allergy and Infectious Diseases (NIAID) and The National Institute of Dental and Craniofacial Research (NIDCR)	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	A5265 is a phase III, open-label, randomized, assessment-blinded clinical trial in non-U.S. sites to compare the safety and efficacy of topical gentian violet (GV) to that of oral nystatin. Therapy will be considered as failed if participants have no clinical improvement (assessed by severity and extent of pseudomembranous candidiasis) during either treatment regimen. Evaluation of signs and symptoms of oral candidiasis (OC) will be done by an evaluator who is blinded to treatment assignment. Quantification of colony forming units (CFUs) of Candida species (spp.) and assessment of the emergence of resistance will be performed using an oropharyngeal swab and a second specimen from oral rinse/throat wash will be collected and stored for future testing		
Update:	A total of 15 participants were enrolled and all completed required study follow up period. On September 27, 2012, there was a Data Safety Monitoring Board (DSMB) review of the interim data for A5265 through July 19, 2012 (165 subjects). Following DSMB recommendations, accrual was temporarily stopped at all participating sites. DSMB recommendations will be addressed in a new protocol version before restarting enrollment again.		
Project Name:	Addressing the Fourth Delay: Improving Communitybased Accountability for Maternal and Newborn Health		
Investigator(s):	Christoffersen-Deb, A. Songok, J. Ruhl, L.		

	Fazen, L.		
Start Date:	12/1/2011	End Date:	12/1/2013
Sponsors:	Grand Challenges Canada	Direct Cost (USD):	\$997
Site(s):	Mosoriot, Teso, Port Victoria		
Project Description:	<p>This project seeks to address a critical fourth delay that sustains high rates of maternal and neonatal mortality in Western Kenya: the delay in a community's accountability to its mothers and infants. An innovative information technology platform that fosters rapid communication and feedback between mothers, their communities, and their healthcare providers called the Mother-Baby Health Network will be developed.</p> <p>This information platform will accomplish three primary objectives: (1) Facilitate home and group-based care through Community Health Workers (CHWs) to improve collective advocacy; (2) Provide communities with the capabilities to activate an emergency alert system; and (3) Foster transparency in community and health system responsiveness to maternal and newborn health. CHWs will be equipped to use clinical decision-support on Android phones to correctly triage women and newborns for care. Integrated with SMS messaging, they will be capable of notifying healthcare providers, alerting nearby GPS-tracked Mother-Baby Taxis in an emergency transport system, and activating a personalized community of Mother-Baby Advocates to mobilize local resources.</p> <p>The Mother-Baby Health Network will strengthen dialogue between communities and facilities to create a sustainable, community-driven demand for accountable maternal and newborn care at all levels of care. Recognizing that 'it takes a village', the Mother-Baby Health Network will provide communities in western Kenya with the information and communication tools they need to ensure that every mother and child has access to essential care at time of delivery and within the first 48 hours of birth.</p>		
Update:	Focus group discussions and barazas have been held. CHWS have been visited to reinforce the 48 hour visit. Meetings have been held with community leaders in Kosirai.		

Project Name:	Antibiotic Sensitivity Patterns Among Post-Mortem Bacterial Isolates. A Sub-Study In The Autopsy Study, Version 1.0, October 31, 2011 (AST Study)		
Investigator(s):	Kwobah, C. Siika, A. Mwangi, A. Swierczewski, B. Odundo, E.		
Start Date:	04/12/2012	End Date:	06/30/2012
Sponsors:	NIH-NIAID	Direct Cost (USD):	Not Reported
Site(s):	MTRH KEMRI/Walter Reed Program, Kericho for sample processing		
Project Description:	The Autopsy Study was initiated in February 2010. The study aims to determine causes of death in HIV-infected patients who die while on antiretroviral therapy (ART). Part of the study procedures include microbial (bacterial, mycobacterial and fungal) cultures from body fluids and tissues including blood, bone marrow, cerebrospinal fluid, lung, spleen, stool, pus and any abnormal collections of fluid found in the bodies during autopsies. The AST sub-study aims to conduct antibiotic susceptibility testing on bacterial isolates.		
Update:	Antibiotic sensitivity testing is ongoing in tandem with accrual from the main Autopsystudy.		
Project Name:	Anticoagulation Project		
Investigator(s):	Pastakia, S. Manji, I. Karwa, R. Akwanalo, C. Saina, C. Schellhase, E. Miller, M. Maina, M. Kanyi, J.		
Start Date:	12/1/2008	End Date:	12/31/2012
Sponsors:	Purdue University College of Pharmacy; Indiana Hemophilia and Thrombosis Center	Direct Cost (USD):	\$50,000
Site(s):	MTRH Webuye Hospital		
Project Description:	A comprehensive pharmacist run anticoagulation care management system customized to a resource constrained setting has been created and implemented. The primary interventional element of this program is the creation of an organized system for INR monitoring of patients requiring anticoagulation with warfarin.		

Update:	Retrospective analysis on the unique dynamics of thrombosis in HIV patients is currently ongoing. Preliminary data on the same was presented as an oral presentation at the American College of Chest Physicians annual meeting in October 2012, by Dr Sonak Pastakia. A manuscript for publication on this analysis will be submitted in a few months.		
Project Name:	Assessment and Treatment of Pain in MTRH		
Investigator(s):	Vreeman, R. Owino, C. Huang, K. Gramelspacher, G. Njuguna, F. Strother, M. Hagembe, M. Monahan, P. Tabbey, R.		
Start Date:	3/26/2011	End Date:	3/26/2012
Sponsors:	Indiana University School of Medicine Department of Medicine	Direct Cost (USD):	\$1,000
Site(s):	MTRH		
Project Description:	<p>Pain is often inadequately evaluated and treated in sub-Saharan Africa.</p> <p>The objectives of this study were to assess pain and pain treatment in 400 hospitalized patients at a national referral hospital in western Kenya, and to identify factors associated with pain and pain treatment.</p> <p>Using validated Kiswahili versions of two single-item pain assessment tools, the Numerical Rating Scale and the Faces Pain Scale-Revised, patients' pain levels were determined. Additional data collected included patient demographics, prescribed analgesics, and administered analgesics. Mean pain ratings and Pain Management Index (PMI) scores were calculated.</p> <p>Averaged between the NRS and FPS-R, 80.5 percent of patients endorsed pain and 30 percent of patients reported moderate to severe pain. Older patients, patients with HIV, and cancer patients had higher pain ratings. 66 percent of patients had been prescribed analgesics at some point during their hospitalization, the majority of which were non-opioids. A majority of patients (66 percent) had undertreated pain (negative scores on the PMI).</p> <p>In conclusion, this study shows that hospitalized patients in Kenya are experiencing pain and that this pain is often under-treated.</p>		
Update:	The second phase of our project was submitted for publication and published in BMC Palliative Care in July 2012.		

Project Name:	Awareness Of Breast Cancer, Among Men And Women In Western Kenya		
Investigator(s):	Asirwa, C. Busakhala, N. Inui, T. Naanyu, V. Wachira, J. Njiru, E. Strother, M. Mwangi, A. Loehrer, P.		
Start Date:	10/1/2011	End Date:	7/1/2014
Sponsors:	Walther Cancer Foundation	Direct Cost (USD):	\$1,200,000
Site(s):	Mosoriot, Burnt Forest, Mt. Elgon		
Project Description:	This is a questionnaire based study to evaluate the awareness of breast cancer among men and women in Western Kenya. This includes questions related to their knowledge of risks for breast cancer, signs and symptoms and health seeking behaviour		
Update:	We received a formal IREC approval on August 30, 2012. Breast screening was conducted in three sites and in the process, a total of 734 participants were recruited from Mosoriot, Turbo and Kapsokwony, Mount Elgon. A Redcap database is being designed for data entry.		
Project Name:	Biomarkers of Vincristine Toxicity in Kenyan Children		
Investigator(s):	Renbarger, J. Njuguna, F. Skiles, J.		
Start Date:	6/23/2011	End Date:	6/30/2014
Sponsors:	NIH	Direct Cost (USD):	\$8,743
Site(s):	MTRH		
Project Description:	This study evaluates the presence of peripheral neuropathy induced by Vincristine in Kenyan children receiving chemotherapy. The main purpose is to assess whether the genetic makeup of each child (particular the genotype of CYP3A5) influences drug exposure and subsequent vincristine toxicity.		
Update:	At present, 91 subjects have been enrolled in the study. An IREC amendment requesting permission to increase our sample size and diagnostically target our population (by changing from patients with any cancer for which vincristine is utilized in the therapy to only those patients with ALL or NHL) has been submitted and is pending approval.		
Project Name:	Building Competencies through Bilateral International Exchanges-Using Qualitative Methods to Measure the Impact on Pediatric Residents from Host and Visiting Countries in		

	Professionalism, Communication and Systems-Based Care		
Investigator(s):	Litzelman, D. Ayaya, S. Umoren, R. Woodward, J. Vreeman, R. Palmer, M. Stelzner, S. Lorant, D. Riner, M.		
Start Date:	11/27/2007	End Date:	6/30/2014
Sponsors:	IU Office of Research in Medical Education	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	This study uses focus groups to assess the impact of resident exchange project on participating residents from Indiana University School of Medicine (IUSOM), Moi University School of Medicine (MUSM), and Universidad Autonoma del Estado de Hidalgo Health Sciences Campus (UAEH) particularly related competencies in Professionalism, communication, Systems Based Practice, and Practice Based learning and improvement.		
Update:	Will recruit additional Kenyan registrars from the 2011 and 2012 groups that have completed the IU elective once study has been reapproved by IREC.		
Project Name:	Causes of early mortality in HIV-infected Africans on antiretroviral therapy		
Investigator(s):	Siika, A. Chumba, D. Buziba, N. Ayikukwei, R. Tierney, W. Wools-Kaloustian, K. Carter, J. Yiannoutsos, C.		
Start Date:	7/1/2009	End Date:	6/30/2013
Sponsors:	NIH-NIAID	Direct Cost (USD):	\$448,880
Site(s):	MTRH		
Project Description:	The autopsy study aims to determine the causes of early mortality in AMPATH -enrolled HIV-infected African patients on ART. The central hypothesis in this study is that the vast majority of early deaths in HIV infected African patients on ART are caused by treatable infectious complications. The rationale behind this research study is that interventions to interrupt early death in HIV-infected patients on ART are more likely to succeed if they		

	<p>target cause-specific mortality. Further, solutions to HIV care and treatment challenges in sub-Saharan Africa are more likely to be found if the research conducted addresses the region's specific healthcare needs and the results of such research can be translated into local practice.</p> <p>The study has three sub- studies which have been approved by Institutional Review Ethics Committee (IREC). Two are currently running (AST_ Substudy and Malaria) while one (DOM Study) has temporarily been halted due to unavailability of funds to run more TB isolates.</p> <p>The study has two specific aims:</p> <ol style="list-style-type: none"> 1. To establish the causes of death by performing detailed pathological autopsies in patients who die in the first 12 months of ART. 2. To develop a verbal autopsy questionnaire that is accurate, specific to HIV infection, and appropriate for identifying causes of death in resource constrained settings. 		
Update:	<p>IREC/IRB approved 400 pathological autopsies and 400 verbal autopsies on the next of kin of the deceased. Accrual to date is 321 pathological autopsies and 321 verbal autopsies</p> <ul style="list-style-type: none"> • <i>Pathological Autopsies</i> – The study has so far conducted a total of three Central Review Board (CRB) to ascertain causes of death (September 2010, July 2011, April 2012 and Nov 2012). Causes of death for 262 participants have been ascertained. • <i>Verbal Autopsies</i> – The study conducted a total of four CRB to ascertain causes of death using verbal autopsy (September 2010, September 2011, April 2012 and Nov 2012). Causes of death for 312 participants have been ascertained. • <i>Training</i> – The study sponsored two of its staff to participate in antiretroviral therapy training in September 2012. 		
Project Name:	Cervical Cancer See and Treat: How Best to Follow-up		
Investigator(s):	Cu-Uvin, S. Omenge, E. Mabeya, H. Washington, S. Itsura, P.		
Start Date:	9/1/2011	End Date:	6/30/2013
Sponsors:	Not Reported	Direct Cost (USD):	Not Reported
Site(s):	MTRH Mosoriot Turbo Chulaimbo		
Project	This is a cross sectional study involving 660 HIV-infected women attending 4 AMPATH-		

Description:	CCSPP (Cervical cancer Screening and Prevention Program) sites who have undergone VIA and cryotherapy >6 months for cervical dysplasia. Demographic information as well as a full medical history will be obtained. They will undergo a gynecologic examination. Women with suspected frank cervical cancer or current genital tract infection will not be enrolled and will be referred for standard of care. Women with genital tract infection will undergo syndromic treatment and will be eligible to be enrolled 3 weeks after treatment if they have cleared the infection. During the gyn exam, the following will be done for all study participants: VIA, conventional Pap smear, endocervical cytobrush for HPV typing. All women with positive VIA result will undergo colposcopy and biopsy at the next available colpo/biopsy clinic day. Those with negative VIA result will return in 4-6 weeks to receive the results of their Pap smear and HPV typing. If either the Pap smear or HPV typing is abnormal, they will undergo colposcopy with biopsy on the next available colpo/biopsy clinic day. Women with negative VIA, PAP smear and HPV will follow standard of care that is annual screening with VIA. Histological diagnosis will be the gold standard. Women will be asked several questions regarding their experience.		
Update:	Not Reported		
Project Name:	CDC RECORDS Study		
Investigator(s):	Tierney, W. Diero, L. Chemwolo, B. Ayaya, S. Songok, J. Sidle, J. Were, M. Wools-Kaloustian, K. Caloia, D. Spitzer, R.		
Start Date:	9/1/2007	End Date:	12/31/2011
Sponsors:	CDC	Direct Cost (USD):	\$1,131,288
Site(s):	MTRH Mosoriot Turbo Burnt Forest Mother and Baby Hospital		
Project Description:	Develop a primary care module for the AMPATH rural health centers and for MTRH's TB, ANC, and Sick Child clinics. To use this module to help coordinate care among patients whose care is shared by both the primary care providers and AMPATH by adding the primary care data to the AMRS and then producing visit summaries with preventive care reminders.		
Update:	This project ended with successful development and deployment of the modules. Data collection is done, and data analysis and manuscript preparation is under way. Two papers		

	were submitted to the 2013 Medinfo meeting in December 2012.		
Project Name:	Childhood Leukemia in Kenya Identified Through Malaria Slide Review		
Investigator(s):	Vik, T. Njuguna, F. Skiles, J. Moormann, A.		
Start Date:	7/1/2012	End Date:	6/30/2014
Sponsors:	Alex's Lemonade Stand Foundation for Childhood Cancer	Direct Cost (USD):	\$200,000
Site(s):	MTRH Turbo Kitale		
Project Description:	The aim of this study is to improve the case detection rate of leukemia by retrospectively reviewing blood smears done for malaria screening to identify children with leukemia in defined population cohorts. If the case detection rate can be improved by utilizing a common and well established procedure, then there is potential to identify children, refer them earlier for treatment and save lives.		
Update:	The study started in July 2012. Protocols and procedures were established for collecting malaria slides at the main site at Kitale District Hospital. Collection of slides began in September 2012, with the plan to collect 12-18 months of slides at that site. Review of the first set of slides began in 1/2013. No publications have been submitted.		
Project Name:	Comparison of Protein Energy Malnutrition and Malaria Levels in AMPATH and Non-AMPATH COBESCentres in Western Kenya		
Investigator(s):	Taylor, K. McDowell, M Kwena, A. Simeon, J. Mining, S. Wakhisi, J.		
Start Date:	8/1/2011	End Date:	8/1/2013
Sponsors:	Moi University	Direct Cost (USD):	\$7,600
Site(s):	Mosoriot Turbo Burnt Forest Amukura Naitiri		

	Chulaimbo Nambale		
Project Description:	The main objective of the study is to determine the nutritional status of children in COBES AMPATH and non-AMPATH centres. In addition, this study seeks to ascertain if the presence of AMPATH has been beneficial in elevation of malnutrition in some centres.		
Update:	Cross-sectional were conducted using structured questionnaires. Anthropometric measurements were carried out on all children < 5 years old. Stunting, Wasting and Underweight appeared to be lower in AMPATH centres when compared to non-AMPATH centres implying the beneficial presence of AMPATH in the community. Presented to 8th Moi University Annual International conference, Sept., 2012.		
Project Name:	Computerized Counseling to Promote Positive Prevention and HIV Health in Kenya (CARE+ Kenya)		
Investigator(s):	Kurth, A. Siika, A. Sidle, J. Ayuku, D. Baliddawa, J. Fortenberry, J, D. Wools-Kaloustian, K.		
Start Date:	8/14/2009	End Date:	6/30/2013
Sponsors:	NIH-NIMH	Direct Cost (USD):	\$1,810,361
Site(s):	MTRH Burnt Forest		
Project Description:	<p>The specific aims of this project are:</p> <ol style="list-style-type: none"> 1. Adapt a theoretically driven computerized counseling intervention (CARE+ Kenya) for use in Western Kenya (1st 18 months). <ol style="list-style-type: none"> 2.1.A. Conduct interviews with up to 25 HIV-positive urban and up to 25 rural men and women patients from the Academic Model Providing Access to Healthcare (AMPATH) to understand HIV and computer training needs. Conduct two staff focus groups (n~16) to assess positive prevention and ART adherence support practices, beliefs about patient computer use and training needs. 2.1.B. Using above, modify intervention content, translate and record audio files into local Kiswahili, and adapt skill-building videos on 'positive health' (prevention, disclosure, ART adherence, reproductive health, etc.). 2.1.C. Conduct iterative software usability testing with 10 urban and 10 rural patients (n=20) and 8 staff. Perform three day test-retest reliability assessment to establish psychometric performance of measures. 2.2 RCT. Establish biological and behavioral efficacy of a longitudinal HIV computerized 		

	<p>counseling intervention in Kenya ('CARE+Kenya') (Months 18-42).</p> <p>2.2.A. Longitudinal RCT in an urban and a rural clinic. Randomly assign HIV-positive adults with missed ART doses on self-report, pharmacy refill or pill counts; or unprotected sex in last 6 months, >1 partner in last year, or sexually transmitted infection (STI) in last 3 years; to intervention (n=125) or risk-assessment control (n=125) for baseline, 3, 6, and 9 month sessions. HIV transmission risk will be measured by self-reported unprotected sex with HIV-negative/unknown partner, and trends in <i>C. trachomatis</i>, <i>N. gonorrhoeae</i>, <i>T. vaginalis</i>. ART adherence will be measured by HIV-1 viral load at 0, 6, 9 months, and at all time points, by electronic monitoring, pharmacy refill, self-report, and clinic attendance.</p> <p>2.3 Establish cost-effectiveness of computerized counseling in Kenya (Months 1-48).</p> <p>2.3.A. Follow patients at the two clinics to evaluate standard of care counseling messages and collect patient time-spent data (n=100, at baseline), to determine unmet patient counseling need.</p> <p>2.3.B. Economically evaluate CARE+Kenya. If RCT shows the intervention reduces viral load and transmission risks, we will use a Bernoulli transmission dynamics model to estimate number of secondary HIV infections prevented; then create a cost-effectiveness model to calculate 2 incremental cost-effectiveness ratios: 1) cost/HIV infection averted, and 2) cost/disability adjusted life year (DALY) saved.</p> <p>2.3.C. If CARE+ Kenya is efficacious and efficient, we will develop a proposal for a cluster-randomized trial to assess translational effectiveness of CARE+ Kenya throughout the AMPATH system.</p>
<p>Update:</p>	<p><i>Accrual Update</i></p> <p><i>Target approval by the IREC/IRB:</i></p> <ul style="list-style-type: none"> A. Patient Interviews <ul style="list-style-type: none"> • Burnt Forest=25 • Module 1=25 B. FGD <ul style="list-style-type: none"> • Burnt Forest=25 • Module 1=25 C. Time-Motion Study <ul style="list-style-type: none"> • Burnt Forest=100 • Module 1=100 D. Usability software testing <ul style="list-style-type: none"> • Burnt Forest=10 Participant • Module 1=10 Participant • Burnt Forest=8 Staff

- Module 1= 8 Staff

Accrual since beginning of study:

A. Patient Interviews

- Burnt Forest=24
- Module 1=15

B. FGD

- Burnt Forest=10
- Module 1=20

C. Time-Motion Study

- Burnt Forest=100
- Module 1=100

D. Usability software testing

- Burnt Forest=10 Participants
- Burnt Forest=5 Staff

Accrual since last update:

A. Usability software testing

- Burnt Forest=10 Participants
- Module 1=11 Participants
- Burnt Forest=5 Staff
- Module 1=5 Staff

B. RCT

- Burnt Forest = 109
- Module 1 = 126

Achievements

The study has successfully exited majority of our study participants in Module1 and expect to have exited all participants in Burnt Forest by end of February 2013.

The IRBs of each institution in the study approved the following amendments:

- a) Rewording the study's policy on reimbursement of participants for travel to study sites to better reflect participant needs.
- b) A questionnaire form for conducting patient exit interviews capturing participant feedback and experiences with the CARE+ Tool. This will allow the CARE+ Tool to be adjusted to incorporate changes as needed for future projects.
- c) A questionnaire form for exit interviews questionnaire with a minimum of 30 participants from each of the study sites to be sure that participant feedback is

reflected in future changes and improvements to the CARE+ computerized platform.

d) A continuing approval was granted until June 30, 2013.

Support Visits

The CARE+ Principal Investigator came to Kenya in November to oversee the CARE Plus Kenya team during the exit of study participants from Module1 and Burnt Forest and meet with the data team to discuss study timelines. This was a follow-up to a September 2012 site visit by the NYU Study Coordinator.

Psychological Findings

Some of the psychological findings we have documented for Module1 and Burnt forest since recruitment began were as follows:

- Depression
 - Module1= 41
 - Burnt Forest= 10
- Intimate Partner Violence (IPVs)
 - Module1= 118
 - Burnt Forest= 68
- Suicidal thoughts
 - Module1= 77
 - Burnt Forest= 18

All participants were referred by the study team to the psychosocial department for ongoing treatment and care including follow-up psychological assessments.

Lab Testing Results

The following findings have been documented since recruitment began:

<u>Burnt Forest</u>	<u>Baseline</u>	<u>Exit</u>
<i>Viral Load >5000 copies/ml</i>	16	0
<i>Neisseria gonorrhoeae Positive</i>	2	1
<i>Chlamydia trachomatis Positive</i>	2	0
<i>Trichomonas Positive</i>	10	0
Module 1	Baseline	Exit
<i>Viral Load >5000 copies/ml</i>	25	11
<i>Neisseria gonorrhoeae Positive</i>	4	2
<i>Chlamydia trachomatis Positive</i>	2	1
<i>Trichomonas Positive</i>	3	0

	<p>Challenges</p> <p>Participant retention is an ongoing challenge. Since the study began, 25 participants have been lost to follow-up. The AMPATH Outreach Department is assisting in tracing these patients.</p>		
Project Name:	Cross-Cultural Histories of Family Care-Giving to AIDS Orphans in Western Kenya		
Investigator(s):	Dickerson-Putman, J. Maithya, H.		
Start Date:	1/15/2009	End Date:	12/1/2013
Sponsors:	IUPUI Research Support Funds Grant	Direct Cost (USD):	\$35,000
Site(s):	Mosoriot Chulaimbo		
Project Description:	The overall goal of the project is to complete an anthropological and clinic-based study that seeks to understand the history of the care-giving experiences of primary providers of care-giving to AIDS orphans in Kenya among two different cultural groups served by the same AMPATH support program.		
Update:	All initial and follow-up interviews have been completed. We are now working on a second draft of codebooks for the two different cultural groups. Our plan is to finalize the codebooks, complete data analysis and submit some publications by the end of 2013.		

Project Name:	Descriptive Study of Patients Seeking Emergency Care in Western Kenya		
Investigator(s):	House, D. Nyabera, S. Kurt, Y.		
Start Date:	01/01/2011	End Date:	12/20/2012
Sponsors:	Not Reported	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	Descriptive study of patients seeking emergency care at MTRH for the year of 2011. Data includes demographics, diagnosis, and disposition. The data will allow for assessment of needs for the department.		
Update:	Study has ended and manuscript has been submitted for publication.		
Project Name:	Diabetes Mellitus and Glucose Intolerance in HIV Patients in Western Kenya		
Investigator(s):	Carter, J. Kirui, N. Kamano, J. Diero, L. Chege, P. Pastakia, S. Gardner, A. Mwangi, A.		
Start Date:	9/3/2012	End Date:	8/31/2015
Sponsors:	Not Reported	Direct Cost (USD):	Not Reported
Site(s):	MTRH Webuye Hospital		
Project Description:	The goal of this study is to determine the association between diabetes mellitus, glucose intolerance, and HIV among HIV positive patients in Western Kenya. In this study, we propose that HIV and ART use increases the risk of diabetes mellitus and glucose intolerance among HIV patients in Western Kenya.		
Update:			
Project Name:	Drug resistance in HIV infected Children after Failure of Prevention of Mother to Child Transmission in Western Kenya		
Investigator(s):	Kantor, R. Nyandiko, W. Vreeman, R. Songok, J.		

	Diero, L. Kosgei, R. Ayaya, S.		
Start Date:	05/03/2011	End Date:	10/4/2013
Sponsors:	Not Reported	Direct Cost (USD):	Not Reported
Site(s):	MTRH Turbo Kitale		
Project Description:	The project seeks to determine the proportion of children becoming HIV infected despite interventions of pMTCT, and the type, if any of antiretroviral drug resistance in those children who get HIV infected after failure of pMTCT.		
Update:	The study has enrolled a total of 13 participants, 9 at MTRH, 4 at Kitale, and 0 at Turbo. All 13 study participants have been consented. This marks an increase of two patients since the last report -- one at MTRH and one at Kitale. No participants have withdrawn from the study. Participant recruitment remains slow due to few patients turning positive after undergoing the vibrant pMTCT program offered by AMPATH.		
Project Name:	EARNEST: A randomised controlled trial to evaluate options for second-line therapy in patients failing a first-line 2NRTI+ NNRTI regimen in Africa		
Investigator(s):	Wools-Kaloustian, K. Siika, A.		
Start Date:	2/9/2011	End Date:	12/31/2014
Sponsors:	European and Developing Countries Clinical Trials Partnership (EDCTP) & the Medical Research Council	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	<p>EARNEST is a three arm parallel group, open-label, multi-centre, randomised controlled trial. The study will recruit 1200 HIV-infected adults who have taken a first-line NNRTI-based regimen continuously for a total period of at least 12 months, and developed treatment failure defined by modified WHO 2010 criteria as one of the following:</p> <ul style="list-style-type: none"> • New WHO Stage 4 event (with CD4 < 200 cells/mm³ and viral load (VL) > 400 copies/ml) • CD4 < 100 cells/mm³, or CD4 fall to pre-treatment baseline or below, or CD4 < 200 cells/mm³ X 2 with previous CD4 > 400 cells/mm³ (with VL > 400 copies/ml) • VL > 5,000 copies/ml x2 <p>The trial aims to determine whether, in patients failing a first-line NRTI and NNRTI-containing regimen, the use of:</p>		

	<ol style="list-style-type: none"> 1. bPI plus raltegravir (an integrase inhibitor) is superior to standard of care (bPI plus 2 new NRTIs) in achieving good HIV disease control at 96 weeks after randomisation. 2. bPI monotherapy is non-inferior to standard of care in achieving good HIV disease control at 96 weeks after randomisation 		
Update:	The study closed to accrual in April 2011. The majority of study participants are now on their week 80 study follow up. Two participants have since died and one withdrew consent. The other 49 active participants continue to do well.		
Project Name:	Enhancing Infant Feeding Options for HIV Infected Mothers		
Investigator(s):	Wools-Kaloustian, K.. Nyandiko, W. Bucher, S. Musick, B. Nyunya, B. Yiannoutsos, C.		
Start Date:	1/10/2006	End Date:	12/1/2012
Sponsors:	Indiana University Center for AIDS Research	Direct Cost (USD):	\$20,000
Site(s):	Burnt Forest Chulaimbo		
Project Description:	The purpose of this study is to determine if questionnaire administered within the clinic can be used to help decide which HIV- infected women should be encouraged to breastfeed and which should be educated about formula feeding their infants. In addition this study will help us to understand why some women choose to mix breast feeding with other types of foods.		
Update:	Not Reported		
Project Name:	Enhancing Training for Implementation Research in Chronic Disease: CITE/Kenya		
Investigator(s):	Inui, T. Ayuo, P. Siika, A. Litzelman, D.		
Start Date:	10/1/2012	End Date:	9/30/2016
Sponsors:	NIH (Fogarty)	Direct Cost (USD):	\$862,970
Site(s):	MTRH		

Project Description:	<p>An innovative clinical and implementation research training program for Kenyan investigators, one built on the foundation of the highly successful and mature clinical and implementation research core curriculum for young investigators within our IUSM CTSI, will be developed. This program will attract graduate trainees nominated by faculty at Moi University schools of medicine, public health, dentistry, nursing, and possibly young faculty from health-related behavioral and social science programs at Moi.</p> <p>This curriculum will be presided over by seasoned Eldoret-based investigators from the AMPATH research network (especially Dr. Thomas Inui and his 5 co-directors of the AMPATH Field Research program). Trainees who complete the core curriculum will be eligible to compete for resources to propose and conduct research in an implementation research practicum under the supervision of a tailored mentorship panel populated by Moi and international faculty. This research will focus upon a chronic disease of importance to the health of the populations in Western Kenya and will contribute to the improvement of health care processes, including village-based processes, medical and psycho-social services, and integration of care for chronic conditions within the MOH delivery system.</p> <p>The 'laboratory' for this research will be the AMPATH-MOH chronic disease program. The training program will build on the successful AMPATH multi-disciplinary and multi-institutional research foundation already in place, supported by AMPATH's remarkable e-Health infrastructure. This program's graduate training will enable Kenyans to acquire knowledge and skills in health systems and implementation research, enhance their capacity to promote continuous improvement of health care, inform health policy, and acquire leadership and management skills needed to develop, manage and improve chronic disease control programs. The ultimate aim of this proposal is to prepare Moi health professionals to serve as effective change agents and scientific leaders in Kenya's evolving system of care.</p>		
Update:	The first 2 fellows for the CITE/Kenya training program were identified in November 2012 and are expected to matriculate in CITE coursework in Indianapolis in January 2013.		
Project Name:	Evaluating Handheld Clinical Decision Support Tools to Improve Community-Based Delivery of Reproductive and Pediatric Health Services		
Investigator(s):	Christoffersen-Deb, A. Chemwolo, B. Fazen, L. Ruhl, L. Songok, J.		
Start Date:	12/1/2011	End Date:	1/31/2013
Sponsors:	Grand Challenges Canada	Direct Cost (USD):	\$97,360.60
Site(s):	Mosoriot		
Project Description:	The primary aim is to evaluate the effectiveness of a handheld CDS system in a cluster randomized-controlled trial among 89 community health workers (CHWs) in Kosirai district over a 4-month enrollment period. By using data collected on the existing CHW Initial		

	<p>Encounter Form and interfacing with AMPATH's electronic medical record system, we will identify and categorize women according to well-defined antenatal risk criteria and deliver patient-specific 'Smart Forms' to each pregnant woman served by enrolled CHWs. This research has four objectives:</p> <ol style="list-style-type: none"> 1) Evaluate comparatively the effectiveness of handheld CDS to improve community-based health service delivery 2) Evaluate the effectiveness of incorporating patient-specific multimedia Information, Education and Communication (IEC) materials into Smart Forms for generating behavior change among clients 3) Determine the cost-effectiveness of a CDS Smart Forms system employed by CHWs and 4) Assess qualitatively the process of implementation of the Smart Forms system, including the technical specifications, human capacity requirements, and acceptability among providers and clients. 		
Update:	Focus group discussions have been held and all CHWs have been trained and equipped with Android phones.		
Project Name:	Evaluation of A Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy (CAMP study)		
Investigator(s):	Vreeman, R. Nyandiko, W. Inui, T. Wanzhu, T. Ayaya, S. Downs, S. Carroll, A. Tierney, W. Marrero, D. Blaschke, T. Arpadi, S. Bell, D.		
Start Date:	9/11/2009	End Date:	2/28/2014
Sponsors:	National Institute of Mental Health (NIH-NIMH) and USAID/PEPFAR	Direct Cost (USD):	\$1,336,011
Site(s):	MTRH Turbo Webuye Hospital Kitale		
Project	The primary objective of this study is to develop and test a reliable, valid instrument to		

<p>Description:</p>	<p>measure pediatric ART adherence for children ages 0 to 14 years in western Kenya and to evaluate which administration strategy yields the most accurate information about children's ART adherence. We will pursue the following four specific aims:</p> <ul style="list-style-type: none"> • Aim 1: Develop a reliable, valid comprehensive pediatric ART adherence measurement questionnaire (CAMP - Comprehensive ART Measure for Pediatrics); • Aim 2: Develop a reliable, valid, short-form version of the pediatric ART adherence measurement tool (SF-CAMP) for use as an adherence screening measure in busy clinical care environments; • Aim 3: Evaluate the field- readiness, implementation feasibility, and clinical utility of CAMP and SF-CAMP within the AMPATH HIV clinical care system in western Kenya; and • Aim 4: Evaluate the reliability and validity of this measurement tool in a clinic-based care setting compared to a home-based care setting.
<p>Update:</p>	<p>Validation of Adherence Measures (CAMP Phases 1 and 2):</p> <p><i>Phase 1</i></p> <p>A battery of ART adherence measurement items were compiled for testing in Kenya from both literature review and formative qualitative work. Items were compiled, translated into Kiswahili, and adapted to increase face validity through cognitive interviews with pediatric caregivers and HIV-infected children ages 13-18 years. The interviews were transcribed and coded, with data for each measurement item summarized qualitatively and quantitatively. A testing report with recommendations for item adaptation was created and used to modify the adherence measurement items. A manuscript describing the findings of the cognitive interviews on adherence measurement items is now in press at the International Journal of Behavioral Medicine.</p> <p><i>Phase 2</i></p> <p>The clinical research phase of the project assessing the reliability and validity of the pediatric ART adherence measurement items for HIV-infected children in Kenya was completed. A total of 211 participants were enrolled with 200 HIV-infected children on ART completing six months of comprehensive monthly adherence assessments, MEMS[®] monitoring of dose timing, plasma drug concentrations, and clinical follow-up including CD4 counts. Data analyses to finalize a validated, comprehensive adherence measurement questionnaire (the CAMP questionnaire) are almost complete. Extraction of questionnaire items to test as a short form (SF-CAMP), to evaluate as per Specific Aim 2 in a cohort of 100 children is ongoing.</p> <p><i>Phase 3</i></p> <p>In the first quarter, Phase 3 of CAMP will be launched. During this phase the validity of a short-form of the adherence assessment tool will be assessed in a sample of 100 children. Comparison of Home-Based and Clinic-Based Adherence Measurement: (Phases 4&5, PEPFAR PHE Funding): These research activities examine home- vs. clinic-based strategies of adherence measurement yield in this setting. We are assessing whether administering the comprehensive adherence assessment items in a home setting yields more reliable or</p>

	<p>valid data than the clinic-based assessments using the same questionnaire items.</p> <p><i>Phase 4</i></p> <p>The feasibility of these measurement strategies were assessed, enrolling 41 children from the Turbo and MTRH clinics and ultimately assessing 40 with either home- or clinic-based evaluations.</p> <p><i>Phase 5</i></p> <p>Phase 5 was successfully implemented over the past 6 months and focused on activities to eliminate longitudinal follow-up. Comprehensive pediatric adherence assessments were conducted at four AMPATH clinical sites: MTRH, Turbo, Webuye, and Kitale. A total of 405 participants were enrolled in the MTRH, Webuye and Turbo and Kitale sites, of which 302 were randomized to clinic assessments and 105 to the home and clinic group. Only 4 participants have withdrawn from the study. Adherence assessments have been completed for 387 children. Data entry and subsequent analysis of the home- vs. clinic-based adherence assessments will begin in January of 2013.</p>		
Project Name:	Feasibility Intervention Trial of Two Types of Improved Cook Stoves in Three Developing Countries		
Investigator(s):	Miranda, J. Menya, D. Checkley, W. Carter, J. Ogaro, F. Diero, L. Mwangi, A.		
Start Date:	7/1/2011	End Date:	06/30/2012
Sponsors:	NHLBI	Direct Cost (USD):	\$76,239
Site(s):	Ndanai Sub-Location Burnt Forest		
Project Description:	<p>This is a multi-center community-based feasibility trial in which improved cook stoves with a chimney are installed in 40 rural households of women aged 20 to 49 years at each of the three sites. All households will have a baseline observational period of 4 months in which outcome, environmental, and behavioral data will be collected longitudinally. Thereafter, 20 households will be randomly assigned to receive a commercially-available, improved cook stove with a chimney or a locally-constructed improved cook stove with a chimney. Behavioral, compliance, outcome and exposure data will be collected longitudinally for 4 months. Exposure assessments will include particulate matter and carbon monoxide. Respiratory outcome assessment will include spirometry, carboxyhemoglobin, exhaled nitric oxide and diffusing capacity of the lung for carbon monoxide. At the end of 4 month period, households that received the Envirofit improved cook stoves will have their cook stoves switched with the locally-constructed improved cook stoves and vice versa, and all households will be followed for another 4 months. At the end of the year, all participants</p>		

	will be asked which cook stove they prefer and will be asked provide information on preferences, practices, and use patterns that influenced their final choice.		
Update:	Enrollment began on December 10, 2012, and . 32 households have been enrolled to date. There are 14 pending enrollments .		
Project Name:	Health Facility Incentives to Improve Adherence to Malaria Diagnostic Test Results		
Investigator(s):	O'Meara, W. Menya, D. Armstrong, J. Manji, I.		
Start Date:	4/1/2012	End Date:	3/31/2014
Sponsors:	NIH	Direct Cost (USD):	\$250,000
Site(s):	Not Reported		
Project Description:	<p>Global investments in controlling malaria have led to some exciting reductions in the burden of malaria. In some areas, malaria-related deaths have dropped by more than 90 percent. As malaria transmission declines, a greater fraction of pediatric fevers are from other causes. However, these fevers continue to be treated as malaria, often despite the availability of diagnostic testing. In a typical rural health facility in Kenya, more than 90 percent of febrile patients are prescribed an antimalarial when no diagnostic tests are available. Even when microscopy or rapid diagnostic tests (RDTs) are available, between 50-80 percent of patients with a negative test are nonetheless prescribed antimalarials. Inappropriately treated fevers in children can lead to serious consequences for the patient and can accelerate the spread of drug resistance. In addition to the risk to patients, overuse of antimalarials also puts a financial strain on the government health system. This project aims to test an innovative, sustainable financial incentive designed to reduce the number of non-malarial fevers that are treated inappropriately with antimalarial drugs.</p> <p>This study will test a financial incentive targeted at the health facility to determine if it improves adherence to diagnostic results and clinical protocols. Eighteen rural health facilities in western Kenya will be enrolled and randomly allocated to one of two arms. We will compare the effectiveness of clinical and technical training in diagnosis of malaria alone (Arm 1) to training plus financial incentives linked to prescription practices (Arm 2) in improving diagnosis and treatment of malaria and non-malaria fevers. The practice of prescribing antimalarials to patients with a negative diagnostic will be compared between facilities with and without the incentive structure. Secondary outcomes will include sensitivity and specificity of routine microscopy at health centers, use of alternative treatments for slide negative fevers, and frequency of stock-outs of antimalarial drugs. This project will be conducted in collaboration with Kenya's Division of Malaria Control and avenues to roll-out the intervention, if successful, will be actively explored.</p>		
Update:	1. The Study was launched and randomization done in two phases; one for the facilities in the Western Province region and another for the facilities in the Rift-Valley Province region. In both, representatives from the Division of Malaria Control in Kenya were in		

	attendance. 2. Baseline data has been collected. 3. Data collection started and is ongoing on a monthly basis. 4. The first quarter for the financial incentives calculation for the facilities in the Western Province ended in December 2012.		
Project Name:	Improving Diabetes Management and Cardiovascular Risk Factors Through Diabetes Peer Group Education In Western Kenya		
Investigator(s):	Bloomfield, G. Kamano, J. Nyabundi, J. Pastakia, S. Park, P. Wambui, C.		
Start Date:	2/13/2013	End Date:	10/15/2013
Sponsors:	Fogarty - NIH, NHLBI - NIH, Duke Global Health Institute	Direct Cost (USD):	\$15,000
Site(s):	MTRH Ziwa		
Project Description:	This project will seek to assess the hypothesis that diabetes education through peer support groups in western Kenya will be feasible and significantly improve diabetes knowledge-base and diabetes control in comparison to routine care.		
Update:	Not Reported		
Project Name:	Increasing Animal Source Foods in Diets of HIV-Infected Kenyan Women and their Children		
Investigator(s):	Ernst, J. ETTYANG, G. Neumann, C. Nyandiko, W. Siika, A.		
Start Date:	10/1/2006	End Date:	7/31/2013
Sponsors:	NIH	Direct Cost (USD):	\$2,943,346
Site(s):	MTRH Turbo Soy Mautuma		
Project Description:	The study is a three arm randomized, blinded and controlled nutrition intervention trial that tests the effect of iso-caloric biscuit supplements of meat, soy or wheat protein added		

	to the diets of drug naive HIV-infected Kenyan women and their children-8 years and younger and who live in the Turbo environs and who receive care at one of the AMPATH clinics (Turbo, Soy, Mautuma, and MTRH). The women are of reproductive age and at enrollment WHO stage I or II. The biscuits are provided five days a week (Monday to Friday) to subject mother and child, using directly observed therapy (DOT) for 18 months. The outcome variables include estimates of lean and fat mass, quality of life, strength measures, biochemical indicators of nutritional status, indicators of immune function, measures of inflammation, nutrient intake, food security, measures of growth and development in children and activities of daily living.		
Update:	Data collection was completed June 2012. Project activities included data entry and data cleaning. A no cost extension was granted until July 31, 2013.		
Project Name:	Indiana University-Moi University Academic Research Ethics Partnership (IU-Moi AREP)		
Investigator(s):	Meslin, E. Ayuku, D. Were, E.		
Start Date:	5/31/2012	End Date:	5/31/2017
Sponsors:	NIH – Fogarty International Center	Direct Cost (USD):	\$1,250,000
Site(s):	MTRH Moi University		
Project Description:	The IU-Moi AREP is funded for five years with a \$1.25 million grant from the Fogarty International Center at the National Institutes of Health to establish a new research ethics training partnership with colleagues at Moi University in Eldoret, Kenya. IU-Moi AREP is a curriculum development and training initiative that builds on longstanding partnerships and collaborations in East Africa. IU-Moi AREP has developed two Masters' degree programs: one at Indiana University-Purdue University Indianapolis and one at Moi University in Eldoret, Kenya. These graduate programs have common overlapping components, joint advisory committees, shared dissemination plans and harmonized evaluation strategies. Both programs include a curriculum involving required core courses, electives and a practicum experience, part of which is taken at the counterpart university. Besides, each IU-Moi AREP partner convenes an annual Teaching Skills in International Research Ethics (TaSkR) workshop to provide training to approximately 40 faculty and students each year.		
Update:	Of the ten students enrolled in the Moi University Master of Science in International Health Ethics program academic year 2011-12, only six students attended the Indy Practicum due to budgetary constraints. The remaining four students undertook their practicum in selected reputable organizations within Kenya. Prior to their travel, the students were given practicum orientation lessons by Dr. Rose Ayikukwei and previous practicum students. Six students travelled to Indiana University on September 14, 2012, to participate in a six		

	<p>week practicum experience that included lectures focused on the NIH specified topics in the responsible conduct of research: conflict of interest; research with animals; history of research with human subjects; policies concerning research with human subjects; research misconduct policies; safe laboratory practices; mentor/mentee relationships; research with human biological material; scientists as responsible members of the society; data acquisition/management; responsible authorships to publications; peer review and interdisciplinary approaches to contemporary issues in bioethics. The students attended additional lecturers offered in the following IUPUI courses: GRAD-G 504 Introduction to Research Ethics; PHIL-P 547 Foundations of Bioethics. They also completed a two day coordinator education program and spent a day meeting with researcher and staff bioethicists at Eli Lilly & Company.</p> <p>In addition to group activities listed above, each student was assigned an IUPUI faculty member as a mentor for their capstone research project. Students met weekly with their mentors and presented a work in progress report during the last week of the practicum receiving constructive feedback from their fellows and faculty members. The practicum students, along with the PI Eric Meslin and Co-PIs David Ayuku and Tom Inui actively participated in the Indiana Global Health Research Conference Center during the period October 3-5, 2012. The conference brought together faculty from all three research-intensive Indiana University and Regenstrief investigators. At the conference Dr. Meslin presented the keynote paper for this focus entitled 'Taking Stock of the Moral Foundations of International Health Research Ethics: Pragmatic Lessons for the IU-Moi Academic Research Ethics Partnership.'</p> <p>AREP trainees developed an abstract for research focusing on evaluating disruptions of care and the broader consequences of labor actions in health.</p> <p>The Moi Msc. International Research Ethics program has enrolled twelve students who are currently in their first semester: Allan Sudoi, Akuto Z. Chepoisho, Kimosop S. Kiprotich, Gogo M. Onyango, Penina Biwott, Alfred Kirui, Felishana Cherop, Koskei Alfred, Lodea K. Henry, Christine Ohanga, Wambui A. Sheila and Mwangi W. Elizabeth. The topic based three weeks "short course" at Moi was not held within this period due to budgetary redistribution to allow more students to attend practicum in Indianapolis but future short courses will continue as planned.</p>
Project Name:	International epidemiologic Databases to Evaluate AIDS (IeDEA)
Investigator(s):	Wools-Kaloustian, K. Ayaya, S. Yiannoutsos, C. Somi, R. G. Swai, R. Ngonyani, K. Lyamuya, R. Lugina, E. Sidle, J. Braitstein, P.

	Martin, J. Bangsberg, D. Glidden, D. Deeks, S. Hunt, P. Diero, L. Nash, D. Abrams, E. Batya, E.		
Start Date:	6/20/2006	End Date:	7/31/2016
Sponsors:	NIH	Direct Cost (USD):	\$2,533,231
Site(s):	All Sites		
Project Description:	<p>The International epidemiologic Databases to Evaluate AIDS Initiative (IeDEA) will establish international regional centers for the collection and harmonization of data and the establishment of an international research consortium to address unique and evolving research questions in HIV/AIDS currently unanswerable by single cohorts.</p> <p>High quality data is being collected by researchers throughout the world. The IeDEA initiative provides a means to establish and implement methodology to effectively pool the collected data and thus providing a cost effective means of generating large data sets to address the high priority research questions. Combination of data collected under various protocols is frequently very difficult and not as efficient as the collection of pre-determined and standardized data elements. By developing a pro-active mechanism for the collection of key variables, this initiative will enhance the quality cost effectiveness and speed of HIV/AIDS research.</p>		
Update:	<p>A total of 77,799 study subjects have been added to the IeDEA database since the study began in September 2012. Of those subjects included in the database, 50,907 are female and 26892 are male.</p> <p>IeDEA East Africa continues to have monthly operations conference calls and an executive team conference call every two months. Research IeDEA East Africa co-investigators are actively involved in both international and local working groups. The international pharmaco-vigilance committee is co-chaired by Dr. Braitstein and the IeDEA pediatric working group is lead by Prof. Ayaya and Dr. Wool-Kaloustian. Dr. Diero and Dr. Siika are actively involved with the IeDEA TB working group. Dr. Martin leads the IeDEA oncology working group and Ms. Musick is actively involved in the IeDEA data harmonization working group.</p> <p>Ongoing IeDEA studies:</p> <ol style="list-style-type: none"> 1. IeDEA East Africa Regional Consortium 2. IeDEA for Data Extraction and Analysis for the Initial Projects (Version 1.0.25 October 2007) 3. National Cancer Institute Supplement to East Africa IeDEA: Improving Kaposi's Sarcoma and Lymphoma Diagnostics as well as Assessing Sarcoma Incidence in 		

	Western Kenya		
	4. Engagement in Care Among HIV-Infected Patients in Resource limited Settings' A supplement to leDEA East Africa (Data analysis stage)		
Project Name:	IU Health Cardiovascular Research Biobanking Project		
Investigator(s):	Inui, T. Kimaiyo, S. Bloomfield, G.		
Start Date:	4/30/2012	End Date:	4/28/2017
Sponsors:	IU Health	Direct Cost (USD):	\$1,060,000
Site(s):	MTRH		
Project Description:	<p>Atrial fibrillation is the most common sustained arrhythmia in high-income countries. Recent insights have been made with regard to the genetic variations that may predispose an individual to developing atrial fibrillation. There has long been observed a disproportionately low prevalence of atrial fibrillation among Africans and African-American compared to people of European descent. Whether mutations in the genes known to cause atrial fibrillation are also causing atrial fibrillation among Kenyan patients with this disorder is unknown.</p> <p>Identification of the frequency of mutations in these genes in patients with atrial fibrillation in Kenya may shed light into the causal pathways of atrial fibrillation in this population. Using a case-control (1:2) research design in a Kenyan population with atrial fibrillation, we propose to perform mutational analysis of the coding sequence and flanking splice sites of the KCNQ1, KCNJ2, KCNE2 and KCNA5 genes known to be mutated in familial and lone atrial fibrillation in patients from high-income countries. A thorough phenotyping protocol will be employed which will include clinical assessment, a medical history, echocardiography and electrocardiography. Genetic material will be collected, stored and processed in Eldoret as the first initiative of the Genetic Biorepository Initiative (PI: Inui, Co-PI: Emonyi) and subsequently shipped for analysis of specific alleles at Indiana University. Using a convenience sample of approximately 140 patients with atrial fibrillation and 140 controls, we will demonstrate the frequency of pathological mutations in the aforementioned genes and provide a thorough clinical description of patients with atrial fibrillation including echocardiographic descriptions and the burden of other comorbid illnesses.</p>		
Update:	The atrial fibrillation study is the first of several that may receive support from this IU granting mechanism. This first protocol is under development for submission to the COE and Adult Medicine Working Group for peer review and subsequently to institutional review boards at Moi, Duke, and IU.		
Project Name:	Levels of Breast Cancer Awareness Among Women Volunteering for Breast Cancer		

	Screening in Western Kenya		
Investigator(s):	Inui, T. Busakhala, N. Sirwa, C. Naanyu, V. Wachira, J. Njiru, E. Strother, M. Mwangi, A. Loehrer, P.		
Start Date:	10/1/2011	End Date:	7/1/2014
Sponsors:	Walther Cancer Foundation	Direct Cost (USD):	\$1,200,000
Site(s):	Mosoriot Turbo Mt. Elgon		
Project Description:	The general purpose of this study is to measure women's knowledge on breast cancer. In addition, the study will determine how perceptions (attitudes) affect the decisions women make about going to be screened for breast cancer. The study will also determine the presence of factors that increase a Woman's chances of developing breast cancer. In addition, the study will find out whether women with breast cancer are treated according to standard guidelines. In order to achieve these objectives, we will administer questionnaires to study participants, do fine needle aspiration cytology and get stain breast specimens after surgery for estrogen and progesterone receptors. We will also follow up these participants for one year		
Update:	Formal IREC approval was granted on September 28, 2012. Breast screenings were conducted at three sites and in the process, a total of 588 participants were recruited from Mosoriot, Turbo and Kapsokwony, Mount Elgon and a Redcap database is being designed for data entry.		
Project Name:	Modified Directly Observed Antiretroviral Therapy (M-DART): An Intensive, Nurse-Directed, Home-Centered, Treatment Strategy to Reduce Mortality and Loss to Follow-Up in High-Risk HIV-Infected Patients Initiating Antiretroviral Therapy		
Investigator(s):	Siika, A. Wools-Kaloustian, K. Murage, T. Thirumurthy, H. Goodrich, S.		
Start Date:	8/1/2011	End Date:	12/31/2013
Sponsors:	USAID/PEPFAR	Direct Cost (USD):	\$825,502
Site(s):	Chulaimbo		

	Kitale Busia Port Victoria Khunyangu		
Project Description:	The M-DART study is a randomized clinical trial comparing the effectiveness of a home-based modified directly observed antiretroviral (ART) treatment strategy to clinic-based standard of care in patients with HIV/AIDS in Port Victoria and Khunyangu, Kenya. The aim is to reduce both mortality and the number of patients lost to follow-up after ART therapy is initiated. In addition to these important objective outcomes, it also seeks to determine if M-DART can contribute to an increased quality of life for patients and help to diminish HIV related stigma.		
Update:	Due to study expansion to new sites, more study staff were employed to handle the high number of participants being followed-up. The new staff undertook the HSP test. As of December 1, 2012, 465 participants were enrolled in the study.		
Project Name:	National Cancer Institute Supplement to East African leDEA: Improving Kaposi's Sarcoma, Lymphoma Diagnostics, and Assessing Kaposi's Sarcoma Incidence in Western Kenya.		
Investigator(s):	Wools-Kaloustian, K. Diero, L. Busakhala, N. Jeff, M. Toby, M. Loehrer, P. Strother, M. Czader, M. Leboit, P. McCalmont, T. Asirwa, C. Yiannoutsos, C.		
Start Date:	8/1/2008	End Date:	7/31/2016
Sponsors:	NIH	Direct Cost (USD):	Not Reported
Site(s):	All Sites		
Project Description:	The toxicity and potential side effects of therapy for malignancy justify a standard of care in cancer medicine of tissue-biopsy. Further, an accurate assessment of the epidemiology of HIV-related malignancy requires reliable pathologic diagnosis. This study will help validate local pathology for the diagnosis of Kaposi Sarcoma (KS). The limited resources available to local pathology mandate that most diagnoses are made via H&E staining and immunohistochemistry which are techniques, like many pathology diagnostic tools, open to inter-observer variability in interpretation. Thus the experience of the pathologist is a major determinant in diagnostic accuracy. Quality assurance efforts and continuing evaluation of diagnostic skills are routine practices		

	in the United States to help ensure ongoing reproducibility between pathologists. The present effort will facilitate similar ongoing quality checks and thus increase the reliability of a biopsy-based diagnosis of KS and lymphoma at the selected sites.		
Update:	Punch Biopsies are continue to be done at the AMPATH oncology clinic. Visiting clinicians continue to visit the oncology sites at Busia, Chulaimbo, Kitale, and Webuye. As of this update, clinicians have been trained at Nambale, Busia, and Bumala A. As of November 2012, the study has completed 1,181 biopsies – 1,033 from AMPATH sites and 148 from Non-AMPATH sites.		
Project Name:	Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)		
Investigator(s):	Vreeman, R. Nyandiko, W. Marete, I. Inui, T. Mwangi, A. Hogan, J.		
Start Date:	9/1/2012	End Date:	9/1/2016
Sponsors:	NIH	Direct Cost (USD):	\$1,886,804
Site(s):	MTRH Mosoriot Turbo Burnt Forest Chulaimbo Webuye Hospital Kitale Khunyangungu		
Project Description:	<p>The purpose of this study is to assess the effect of a patient- and family-centered intervention guiding disclosure to HIV-infected Kenyan children using a randomized trial comparing the intervention to routine care. The primary endpoint will be probability of disclosure among children, with secondary endpoints of adherence, clinical outcomes, psychological distress and social outcomes.</p> <p>Phase One, which will last 6 months, focuses on cultural adaptation of the intervention materials through intensive patient participation, including focus groups and cognitive interviewing, selecting narrative components, and training dedicated disclosure counselors.</p> <p>Phase Two consists of a randomized, controlled trial conducted in eight pediatric HIV clinics with comprehensive patient assessments every 6 months for 2 years</p>		
Update:	IRB and IREC approval for the project activities was secured. The study began by organizing and holding focus group discussions with parents, caregivers, and adolescents at three sites. The qualitative analysis of the eleven focus group discussions has begun. Staff were		

	interviewed and hired and an office was opened. Initial development of intervention materials was begun. The study hopes to begin recruitment in April 2013.		
Project Name:	Patient-Reported Outcomes of Cancer Care in Eldoret, Kenya		
Investigator(s):	Hess, L. Naanyu, V. Asirwa, C.		
Start Date:	3/4/2010	End Date:	4/1/2013
Sponsors:	Walther FoundationIU International Development Fund	Direct Cost (USD):	\$23,310
Site(s):	MTRH Moi University IUPUI		
Project Description:	The proposed study is designed to validate and subsequently implement a standardized questionnaire to obtain patient perspectives of their physical and psychosocial well-being (quality of life) during and following cancer treatment. The primary objective of this research is to validate an instrument that can be used to obtain knowledge about the quality of life of cancer patients in Eldoret, Kenya, which will then guide future strategies to improve comprehensive cancer patient care. The specific aims are to determine the validity of the Kiswahili version of the Functional Assessment of Cancer Therapy General scale (FACT-G) by: (1) conducting focus groups of cancer patients in Eldoret to explore the constructs underlying the translation of the FACT-G instrument; (2) revising the translation wording as needed prior to implementation; and (3) administering the final version of the FACT-G along with the previously-validated Patient Health Questionnaire Nine Symptom Checklist (PHQ-9) longitudinally in this population. The FACT-G has been validated in more than 40 languages and is used worldwide to assess cancer therapy, but has yet to be validated in Kenya.		
Update:	The focus group was completed. The validation project is completed. Data QA/QC and analysis is ongoing.		
Project Name:	Prevalence and Impact of Alcohol Use in Patients Enrolling in HIV Care		
Investigator(s):	Wools-Kaloustian, K. Diero, L. Hahn, J. Kulzer, J. Goodrich, S. Bwana, B. Oyaro, P. Aluda, M.		
Start Date:	3/1/2013	End Date:	3/1/2014

Sponsors:	NIH-NIDA	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	Though drug use (including inhalant use) is an increasing problem in East Africa, alcohol remains the most common substance of abuse in our populations. There are limited data on the impact of alcohol use on immune reconstitution, adherence and retention in care within sub-Saharan African HIV- infected populations. Given the high rates of food insecurity and resulting malnutrition, the impact of alcohol use on clinical outcomes in HIV-infected individuals in East Africa may be more profound than that seen in North America. Further exploration of the prevalence of and impact of alcohol use on the outcomes of HIV-infected individuals in sub-Saharan Africa is needed in order to inform HIV-care and treatment programs and assess the need for systems adaptation targeted towards identifying and intervening in individuals with alcohol addiction issues.		
Update:	A protocol has been submitted to IREC for approval.		
Project Name:	Quinolone Use by Patients with Tuberculosis in a Large HIV Treatment Program in Western Kenya		
Investigator(s):	Gardner, A. Siika, A. Carter, J. Pastakia, S. Diero, L. Cohen, T. Musick, B. Simiyu, G. Koech, J.		
Start Date:	01/12/2009	End Date:	12/01/2012
Sponsors:	Not Reported	Direct Cost (USD):	Unfunded
Site(s):	MTRH		
Project Description:	Retrospective analysis of pharmacy and AMRS data to characterize the extent and indications for use of fluoroquinolones among patients in AMPATH and understand the implications for TB control.		
Update:	Manuscript in progress.		
Project Name:	REACH Informatics Center of Excellence		
Investigator(s):	Biondich, P. Siika, A. Braitstein, P. Diero, L. Sidle, J.		

	Downs, S. Hogan, J. Kroenke, K. Mamlin, B. Meslin, E. Nyandiko, W. O'Meara, W. Palakal, M. Rotich, J. Shen, C. Vreeman, R. Were, M. Wools-Kaloustian, K.		
Start Date:	06/01/2009	End Date:	06/30/2014
Sponsors:	NIH-Fogarty International Center	Direct Cost (USD):	\$945,464
Site(s):	MTRH		
Project Description:	The project is a collaboration between Indiana and Moi Universities and the global leadership of the Regenstrief Institute. The program will: <ol style="list-style-type: none"> 1. Provide post-doctoral informatics training to faculty at Moi University and Moi Teaching and Referral Hospital to implement and use health information technology to enhance research and improve health care quality, efficiency and outcomes. 2. Support the training of East Africans so as to support the development, implementation, maintenance, evolution and use electronic health records (EHRs) in low-income countries through didactic and mentored practicum training 		
Update:	The first fellowship student completed a masters degree in health informatics. The second and third fellowship students started their second year of research work in Eldoret. Their research is focused on patient matching, pediatric immunization and clinical decisions support. The fourth fellow started their first year of study at Indiana University in July 2012. <p>The following short courses were held since the last update:</p> <ol style="list-style-type: none"> 1. Forms design training was held with 10 participants from AMPATH and KEMRI CDC, Kenya (July 9-13, 2012) 2. EMR Master Orientation Workshop was held in Nakuru (July 29 – August 2, 2012) 3. Kenya EMR training of trainers in Nakuru (September 10-14, 2012) 4. Kenya EMR Health Managers Orientation Nyanza (September 24 – 25, 2012) 5. Kenya EMR Health Managers Orientation in Kakamega (October 10-11, 2012) 6. Kenya EMR Health Managers Orientation Rift Valley (October 31 – November 1, 2012) 7. Online Redcap trainings for AMPATH research staff (November 9, 16, 23 and 		

	December 7, 2012)		
Project Name:	Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens (REMEMBER)		
Investigator(s):	Siika, A. Lagat, D.		
Start Date:	9/26/2012	End Date:	12/31/2014
Sponsors:	NIAID, Gilead Sciences Inc., and Merck & Co., Inc.	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	In this randomized, open-label strategy trial, participants from RLS who present with advanced HIV disease and will be initiating ART but are without evidence of probable or confirmed TB according to criteria in the current ACTG diagnosis appendix (which will be identified on the case report form [CRF]) will be randomized 1:1 to one of two strategy arms: empiric TB treatment (public health approach, Arm A) or local standard of care (individualized TB treatment approach, Arm B) at study entry. At the 48 week visit, participants will transition to a 48-week follow-up period of non-study-provided treatment and care, with total study duration being 96 weeks. The primary endpoint is survival status at 24 weeks post randomization. AIDS progression, virologic and immunologic response, development of plasma HIV drug resistance, resistance to TB drugs, safety and tolerability of ART and TB drugs, and adherence to ART and TB drugs will also be evaluated as will the relative cost-effectiveness of the two strategies.		
Update:	A total of 16 participants have been enrolled. Two are in the screening phase and their results are pending.		
Project Name:	Renal Study		
Investigator(s):	Wyatt, C. Owino Ong'or, W. Abuya, J. Wools-Kaloustian, K.		
Start Date:	12/10/2007	End Date:	12/10/2013
Sponsors:	Gilead Foundation	Direct Cost (USD):	\$165,000
Site(s):	MTRH		
Project Description:	This study is comparing the performance of equations to estimate kidney functions to a direct measure of kidney function based on the plasma disappearance of iohexol in HIV-infected adults.		
Update:	The study is closed to enrollment and followup and remains open for data analysis only.		

	The primary publication is in submission. We are seeking funds to measure an additional marker of kidney function, cystatin C, in banked serum specimens.		
Project Name:	Screening for Cervical Cancer in HIV positive Kenyan women		
Investigator(s):	Dainty, E. Omeng, O. Cu-Uvin, S. Walmer, D.		
Start Date:	10/11/2011	End Date:	5/1/2013
Sponsors:	NIH (Fogarty International Center; Duke Center for AIDS Research)	Direct Cost (USD):	\$37,000
Site(s):	MTRH Mosoriot Turbo		
Project Description:	This project involves the collection of demographic data as well as cervical swab specimens for HPV genotyping from women with HIV who receive cervical cancer screening through the AMPATH supported program.		
Update:	Data collected, participant recruitment ended April 11, 2012. The study is currently in the data analysis and manuscript preparation phase.		
Project Name:	Survival among HIV-infected Patients with Kaposi's Sarcoma in sub-Saharan Africa in the Era of Potent Antiretroviral Therapy		
Investigator(s):	Wools-Kaloustian, K. Busakhala, N. Martin, J.		
Start Date:	4/1/2013	End Date:	4/1/2014
Sponsors:	NIH-NCI	Direct Cost (USD):	Not Reported
Site(s):	All Sites		
Project Description:	<p>In sub-Saharan Africa, the intersection between endemic human herpesvirus 8 and epidemic HIV infections has resulted in Kaposi's sarcoma (KS) becoming one of the most commonly reported malignancies amongst all adults in the region. Not only is incidence of KS high but the clinical manifestations are substantial as well. Specifically, in the era prior to potent antiretroviral therapy (ART), cumulative one year mortality after HIV-associated KS diagnosis was as high as 60 to 70 percent.</p> <p>Fortunately, based on data following the advent of ART in resource-rich settings, there is now hope for improved KS survival in sub-Saharan Africa now that ART is becoming available. The many differences, however, between resource-rich and resource-limited</p>		

	<p>settings -- particularly in availability of chemotherapy and supportive cancer care -- make extrapolation from resource-rich settings to Africa problematic. While early reports from sub-Saharan Africa in the ART era do show what appear to be improvements in KS survival compared to historical data, these studies are clouded by either substantial losses to follow-up , many patients not actually on ART , small sample sizes and hence imprecise estimates, or being conducted in difficult-to-generalize trial settings . In particular, the studies conducted in the most representative settings also suffer from between 15 to 37 percent lost to follow-up . Because of the obvious concern that these lost may be dead, the nominal survival estimates are nearly uninterruptable. Thus, while ART is now being administered to over 5 million HIV-infected patients in sub-Saharan Africa, we do not yet know its impact on the survival of the most common malignancy of the HIV epidemic.</p> <p>To address these limitations, the overarching objective of this study is to definitively study survival after KS diagnosis in Africa in the contemporary ART era. Our specific aims are to:</p> <ol style="list-style-type: none"> 1. Determine survival after a diagnosis of HIV-associated KS in the ART era in sub-Saharan Africa; 2. Assess among HIV-infected individuals who initiate ART in Sub-Saharan Africa, if presence of KS is associated with excess mortality compared to other HIV-infected patients with concurrent opportunistic infections or equivalent CD4+T cell counts; and 3. Evaluate the pace and determinants of initiation of ART after a diagnosis of HIV-associated KS in Sub-Saharan Africa. 		
Update:	IREC application is under development.		
Project Name:	The Implementation of a Neonatal Nurse Training Program at the Riley Mother Baby Hospital of Kenya		
Investigator(s):	Lemons, J. Gisore, P. Hawk, S. Songok, J. Trautman, M. Bucher, S.		
Start Date:	6/4/2012	End Date:	5/31/2013
Sponsors:	Indiana University School of Medicine, Department of Neonatal-Perinatal Medicine	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	The goal of this study is to evaluate the effectiveness of a neonatal nurse training program in improving the knowledge, patient care practices and processes of nurses working in a neonatal intensive care unit in a resource limited setting. The primary outcome of this study is the impact of the Neonatal Nurse Training Program on nurse competency related		

	<p>to three crucial domains of neonatal nursing care (i.e., thermoregulation, respiratory monitoring, and infection control).</p> <p>The impact of the Neonatal Nurse Training Program on nursing competency will be measured in regards to both (1) knowledge (as evaluated by a multiple-choice questionnaire administered pre/post the training program) and (2) actual patient care practices (as assessed by pre/post training program observations by a trained evaluator in the nursery). Secondary outcomes will include evaluation of process changes related to documenting patient care, as well as outcomes such as NICU mortality rate and length of stay in the nursery. These outcomes will be evaluated primarily via pre/post training program retrospective chart review, and augmented by observational data.</p> <p>We hypothesize that a neonatal nurse training program will significantly improve nurse competency and the quality of patient care as measured by improvement in knowledge, practices, processes and patient outcomes such as mortality. The results of this study will help validate the importance of nursing education and its effect on patient care in the resource limited setting, and if successful, will make an important contribution toward the improvement of nursing practices among staff at one of the largest and busiest referral NICUs in East Africa.</p>		
Update:	Pre-intervention data collection began in June 2012 and was completed in September 2012. The education program took place September 2012, with post-intervention data collection to be completed in January 2013.		
Project Name:	The IU Simon Cancer Center (IUSCC) AMPATH-Oncology Institute (AOI): An Exemplar of Care for the Developing World and a Population-Based Research Environment for IUSCC		
Investigator(s):	Inui, T. Busakhala, N. Asirwa, C.		
Start Date:	7/1/2011	End Date:	6/30/2014
Sponsors:	Walther Cancer Foundation	Direct Cost (USD):	\$1,200,000
Site(s):	Mosoriot Turbo Kapsokwony		
Project Description:	Kenya, like much of the developing world, is rapidly undergoing an 'epidemiologic transition' from a health scene dominated by infectious diseases to one in which the major causes of death and disability are cancer and other chronic diseases. Under these circumstances, applying science to the management and control of cancer has become as relevant to Kenya as it is in the United States. Similarly, what is learned about the prevention and treatment of cancer in the developing world literally has direct relevance to care in the United States. Cancer care and attendant research in Kenya, whose population is the most genetically diverse in the world, will catalyze the discovery of new genes of importance to our fight against cancer, new genomic predictors of cancer, and new genetic variants that predict response to therapy.		

	<p>Recognizing both emerging threats to population health and potential for advancing care and science, the IU Simon Cancer Center (IUSCC) and the IU-Kenya AMPATH Program have been actively pursuing resources to respond. The focus of the partnership is to develop a sustainable and comprehensive academic clinical care program that will serve the citizens of western Kenya, and in the process, create a unique program of international collaboration for patients with, or at risk for, malignancies. The mission of the AMPATH Oncology Institute (AOI) is to be the premier cancer program in Sub-Saharan Africa, noted for excellence in cancer prevention, treatment and palliative care. AOI activities will directly contribute to advances in cancer care, accelerate discoveries in the biology and treatment of cancer, and provide support for the IU Simon Cancer Center's quest to become a federally designated Comprehensive Care Center.</p> <p>Naftali Busakhala will characterize the awareness, beliefs, attitudes and behaviors of women coming to AMPATH's clinician breast exam screening as volunteers, comparing these beliefs to those of a community-based sample of women. He will also characterize the yield of the AMPATH screening program, the kinds of cancers detected, and the quality of care achievable in Western Kenya at present, with comparison against an international standard of care.</p> <p>Chite Asirwa will similarly characterize the awareness, beliefs, attitudes and behaviors of a community-based sample of women, comparing their beliefs to those of their husbands, often a key influence on behavior in traditional societies. Taken together these two studies should reveal a great deal about how to influence women's behaviors and encourage participation in the only breast cancer screening program available presently - clinician examination.</p> <p>Both of these studies will use the BCAM (Breast Cancer Awareness Measure), a survey tool developed in Great Britain. We have worked carefully through the standard BCAM to sort questions into theoretically sound domains, using the Health Belief Model as a framework. Violet Naanyu will be conducting field testing and focus groups to do a culturally appropriate Kiswahili version.</p>
<p>Update:</p>	<p>These protocols were approved by IU IRB, IREC and Oncology Working Groups.</p> <p>In three community screening and surveys 588 women volunteers for screening completed BCAMs, and 737 community men and women completed BCAMs. The project is now in a data-entry phase.</p>
<p>Project Name:</p>	<p>The Prevalence of Markers of Atherosclerosis Among Adult Patients with Congestive Cardiac</p>
<p>Investigator(s):</p>	<p>Velasquez, E. Kimaiyo, S. Bloomfield, G. Carter, J. Maghasi, M. Akwanalo, C. Hogan, J.</p>

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Start Date:	5/24/2011	End Date:	6/30/2012
Sponsors:	NIH/NHLBI	Direct Cost (USD):	Not Reported
Site(s):	MTRH		
Project Description:	Using a case-control research design in a Kenyan population with heart failure, this project will describe the range of etiologies of heart failure within this population. This project will collect pilot data on the burden of atherosclerosis and malnutrition among patients with heart failure at Moi Teaching and Referral Hospital (MTRH) inpatient ward, primary care and cardiology clinics, through the collection of both echocardiographic and serologic studies coupled with clinical assessments; thereby informing hypotheses for larger prospective, regionally-relevant analyses in the future.		
Update:	Data collection was completed in December 2012. Primary data analysis is ongoing.		
Project Name:	The Prevalence of Rheumatic Heart Disease in Western Kenya: an Echocardiographic Study		
Investigator(s):	Corey, R. Kimaiyo, S. Holland, T. Koech, M.		
Start Date:	7/1/2010	End Date:	6/30/2012
Sponsors:	NIH—Fogarty International Center	Direct Cost (USD):	\$15,000
Site(s):	MTRH		
Project Description:	<p>This was an echo-based study looking at prevalence of rheumatic heart disease (RHD) in Western Kenya by performing echocardiography in a representative hospital-based sample of 500 subjects. The central hypothesis is that if echocardiographic screening is conducted on this population, ages 5-30, more silent RHD will be found and a prevalence similar to that reported in the recent literature will be detected.</p> <p>The principal aim of this study is to investigate the prevalence of RHD, as determined by transthoracic echocardiography, in patients (ages 5-30) hospitalized on the orthopedic and surgical wards</p> <p>The intent is to more precisely define the burden of rheumatic heart disease in Western Kenya with the most definitive diagnostic modalities. Results from these investigations would be important in elucidating more inclusive screening criteria for patients at risk for rheumatic heart disease in the general population. More importantly, epidemiologic data derived from our investigations would be central to the development of any community-based primary and secondary prevention campaigns against group A streptococcal infection, acute rheumatic fever and rheumatic heart disease.</p>		
Update:	Enrollment completed in June 2012 and the study closed. The echocardiograms are being over-read by our cardiologists, then the data will be analyzed and manuscript prepared.		

Project Name:	The relationship of Indoor Air Pollution (IAP) Exposure to Isolated Right Heart Failure (IRHF)		
Investigator(s):	Carter, J. Kimaiyo, S. Lagat, D. Sherman, C. Anstrom, K. Hogan, J. Diero, L.		
Start Date:	12/10/2010	End Date:	5/30/2012
Sponsors:	NIH/NHLBI	Direct Cost (USD):	Not Reported
Site(s):	Kaptagat		
Project Description:	<p>Several studies have shown that isolated right heart failure (IRHF) is more prominent in African women than in those living in resource rich nations. Its prognosis is thought to be worse among African women relative to similar patients from the richer economies given their general lack of access to health care and often late presentation of disease. Chronic Obstructive Pulmonary Disease (COPD) is the leading cause of IRHF in resource rich nations. While COPD remains the seventh leading cause of morbidity and mortality worldwide, it remains unclear whether this relationship exists in African women. In resource rich nations it is related to cigarette smoking. Risk factors for the development of COPD in Africa include combustion of biomass/traditional fuels and coal, previous tuberculosis infection, and childhood respiratory infections. Biomass fuels are used extensively throughout Africa, especially in the sub-Saharan area. Typical pollutants that result from the poor burning and ventilation of these fuels include particulate matter, aldehydes, carbon monoxide, hydrocarbons, volatile organic compounds, and nitrogen dioxide. Worldwide, women exposed to indoor smoke are three times as likely to develop COPD as those who cook and heat with electricity, gas, and other cleaner burning fuels. A study of rural South African women found an increased prevalence of COPD due to the burning of cow dung in poorly ventilated houses. The relationship between IAP and COPD needs further investigation in sub-Saharan women.</p>		
Update:	Not Reported		
Project Name:	The Susan G. Komen for the Cure® Tissue Bank at the IU Simon Cancer Center Kenya Project		
Investigator(s):	Storniolo, A. Busakhala N. Lumarai, D.		
Start Date:	7/1/2012	End Date:	11/30/2013
Sponsors:	Susan G. Komen for the Cure	Direct Cost (USD):	\$500,000

Site(s):	MTRH
Project Description:	<p>Triple negative breast cancer, an aggressive form of breast cancer, disproportionately affects African women and premenopausal African-American women. A diagnosis of triple negative disease is particularly devastating because there are no targeted therapies against it and it carries with it an especially poor prognosis. Exactly why women of African descent are more prone to this malicious form of breast cancer is unclear. This question demands increased attention, and the Susan G. Komen for the Cure® Tissue Bank at the IU Simon Cancer Center ('Komen Tissue Bank') is ideally positioned to play a critical role.</p> <p>The Komen Tissue Bank is the first and only biorepository of normal breast tissue in the world. As with many other areas of breast cancer research, we believe that the availability of such normal tissue has the potential to revolutionize our understanding of triple negative disease. Specifically, we believe that comparing normal and triple negative tissue from African donors will allow researchers from Indiana University--and others from around the world--to uncover vital clues regarding the origin of triple negative disease in women of African ancestry and thus speed the discovery of promising therapeutics.</p> <p>After receiving IREC approval, a tissue collection event will be held in Kenya in the summer of 2013. A portion of the tissue collected will remain in Kenya for research and the remaining tissue will be deposited into the Komen Tissue Bank as a resource for breast cancer researchers around the world. As part of this project, there will be a community event to help educate residents about breast cancer and breast health.</p>
Update:	<p>Kenyan Investigators have travelled to Indiana to observe a tissue collection event. Protocol, consent & questionnaire development is in process and will be submitted to IREC. A site visit to Eldoret is planned for the North American team in January 2013.</p>

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